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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,218

04/25/2006

Geena Malhotra

8693.014.US0000

5437

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7590

07/15/2010

Novak, Druce & Quigg LLP
300 New Jersey Ave, NW
Fifth Floor
WASHINGTON, DC 20001

EXAMINER

DOUGLAS, STEVEN O

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

07/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,218	Applicant(s) MALHOTRA ET AL.	
	Examiner /Steven O. Douglas/	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-9 and 11-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-9 and 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,11,12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan (GB 2 195 544).

The Jordan reference discloses a pharmaceutical inhaler that dispenses a metered dose comprising a canister made of a plastic material that is transparent and a metering valve, but fails to disclose the plastic material as being at least partially or entirely polycarbonate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the plastic material be at least partially or entirely polycarbonate, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

In regard to claim 13, the Jordan reference discloses an inhaler (supra), but fails to disclose the canister as being made by injection molding or injection blow molding. Examiner takes Official Notice that injection molding and injection blow molding are commonly known methods of making containers in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the canister by either injection molding or injection blow molding in view of Examiner's Noticed observation of conventionality.

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In regard to claims 14 and 15, the method as claimed would be inherent during normal use and operation of the device.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan (GB 2 195 544) in view of Morris, Jr.

The Jordan reference discloses a pharmaceutical dispenser (*supra*), but fails to disclose markings indicative of the amount remaining in the canister. The Morris, Jr. reference discloses another dispenser having markings 42 indicative of the amount of substance remaining in the dispensing container. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Jordan dispenser to include markings in view of the teachings of the Morris, Jr. reference to indicate the amount of substance remaining in the dispensing container.

Claims 7-9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan (GB 2 195 544) in view of Dickinson et al. (US 6,737,044).

The Jordan reference discloses a pharmaceutical dispenser (*supra*) including a broadly disclosed pharmaceutical formulation, but fails to disclose the formulation of the pharmaceutical being one of salbutamol, ipratropium and budesonide, and a propellant. The Dickinson et al. discloses another pharmaceutical dispenser including a formulation of the pharmaceutical being one of salbutamol, ipratropium and budesonide, and a propellant. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the pharmaceutical formulation as, for example, shown by Dickinson et al. for the broadly disclosed

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formulation of Jordan wherein so doing would merely amount to the substitution of dispensed formulation for another that would work equally as well in the Jordan device.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan (GB 2 195 544) in view of Hutchinson et al. (US 6,352,426).

The Jordan reference discloses an inhaler (supra), but fails to disclose the canister as being made by injection molding or injection blow molding. The Hutchinson et al. reference discloses that injection molding and injection blow molding are commonly known methods of making containers in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the canister by either injection molding or injection blow molding in view of the Hutchinson et al. showing of conventionality.

Furthermore, the method as claimed would be inherent during the normal use and manufacture of the Jordan device as modified by Hutchinson et al.

Response to Arguments

Applicant's arguments filed 5/19/10 have been fully considered but they are not persuasive.

In regard to Applicant's repeated argument/evidence that PET materials expand when exposed to ambient temperatures of 40 degrees C and would not be suitable for use with MDI containers, Applicant's argument and evidence is acknowledged. However, Applicant's evidence is directed to PET materials and not polycarbonate materials which are inherently

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known to be more suitable to exposure of ambient temperatures of 40 degrees C. Such suitability goes to the basis of the decision/settlement of *In re Leshin*.

Furthermore, in regard to Applicant's argument that there is no teaching in Jordan or any other cited reference that shows a polycarbonate, especially one devoid of any interior coating, Examiner acknowledges that none of the references of record, including Jordan, disclose a polycarbonate material. However, as stated in the rejection, polycarbonate materials are well known materials, and it is well settled and held that to select a known material is merely a matter of obvious design choice. In regard to the polycarbonate being one devoid of any interior coating, Examiner reiterates that it is well settled that polycarbonates (i.e. without coatings thereon) are well known in the material arts and Examiner is not modifying the material to have a coating thereon.

In regard to Applicant's argument that Jordan as modified by Hutchinson et al. fails to disclose the injection or blow molding of polycarbonates, Examiner acknowledges that Hutchinson et al. is directed to the injection or blow molding of polycarbonates. However, Examiner is merely relying on Hutchinson et al. to show that injection or blow molding of plastic materials is conventionally known.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Steven O. Douglas/ whose telephone number is (571) 272-4885. The examiner can normally be reached on Mon-Thurs 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven O. Douglas/
Primary Examiner
Art Unit 3771

SD
7/13/10